



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,038	01/09/2004	Avram Reuben Gold	2111-040037	7887
28289	7590	11/21/2006	EXAMINER	
THE WEBB LAW FIRM, P.C. 700 KOPPERS BUILDING 436 SEVENTH AVENUE PITTSBURGH, PA 15219			BRANDT, ADAM CURTIS	
			ART UNIT	PAPER NUMBER
			3771	

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/755,038	GOLD, AVRAM REUBEN	
	Examiner	Art Unit	
	Adam Brandt	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-28 is/are pending in the application.
- 4a) Of the above claim(s) 2-3, 13-14, 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-12 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to the amendments filed on 9/18/2006. Claims 1-3 and 5-28 are pending in the application. Claims 2, 3, 13, 14, and 21-28 have been withdrawn from consideration.

Specification

2. The use of the trademarks REMstar®, Solo®, BiPAP®, Virtuoso®, PAV® have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

3. Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitation proposed by claim 15 has been incorporated into claim 12, but it appears as the Applicant has forgotten to cancel claim 15.

Claim 16 is objected to because it is dependent on a claim that does not further limit the subject matter of the previous claim. The Examiner takes the position that claim 16 is dependent on claim 12 for examination purposes.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 1, 4-12, 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating the particular functional somatic syndrome of fibromyalgia, UARS and OSA/H, does not reasonably provide enablement for treating other functional somatic syndromes such as chronic fatigue syndrome, irritable bowel syndrome, migraine headaches, tension headaches, temporomandibular joint syndrome, Gulf War syndrome, premenstrual syndrome, multiple chemical sensitivity, sick building syndrome, repetition stress injury, side effects of silicone breast implants, chronic whiplash, restless leg/periodic limb movement syndrome. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant has provided disclosure of identifying different patients, each suffering from one of fibromyalgia, UARS and OSA/H; a connection between fibromyalgia and UARS and OSA/H by showing common symptoms; and then provided a clinical example of treating patients suffering from fibromyalgia with positive airway pressure therapy; however, there is no disclosed clinical connection between any of the

Art Unit: 3771

additional recited functional somatic syndromes and UARS or OSA/H that would provide one of ordinary skill with sufficient information to make and use the instant invention without undue experimentation.

It is unclear to the Examiner how these syndromes or symptoms are linked together besides the singular fact they are generally lumped under the same accepted medical term “functional somatic syndromes”. For example, irritable bowel syndrome and orthostatic syncope are linked by the title “functional somatic syndrome” but share little or no symptoms. Therefore, unless it can be demonstrated that the methods set forth will provide successful results for each of the syndromes/symptoms listed without undue experimentation, the disclosure fails to enable one skilled in the art to assess and treat the conditions with out undue experimentation.

Additionally, there is no disclose pertaining to how or to what extent the patient is treated. The disclosure does not discuss if the syndrome is alleviated or if the symptoms are reduced. There is no discussion to the finality of the treatment. There are no method steps defining a practical technique. Treating a patient with an air stabilization technique to cure functional somatic syndrome is a mere conclusion drawn without scientific testing.

The specification does not provide an adequate description how to identify disorders or syndromes with out undue experimentation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 5, 6, 7, 11, 12, 15, 16, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pantino ('910) in view of Thornton ('048).

As to claim 1, Pantino discloses a method of treating functional somatic syndromes comprising the steps of: identifying a patient as having a functional somatic syndrome (e.g. temporomandibular joint syndrome, a known functional somatic syndrome at col.8, lines 50-51); and treating such a patient with an airway stabilization technique (fig.1). Pantino fails to disclose the airway stabilization technique is positive airway pressure therapy.

Thornton teaches a method of stabilizing a patient's airway by employing a combination of positive airway pressure therapy and a mechanical stabilizer (fig.1a). the advantage of using both positive airway therapy with a mechanical stabilizer is to provide a means for adjusting upper and lower teeth arches thereby increasing the opening of the user's breathing passageway to increase the effectiveness of treatments for breathing disorders such as OSA while remaining comfortable for the patient (col.2, line 58-col.3, line 10).

It would have been obvious to modify the method of treating temporomandibular joint syndrome of Pantino to include positive airway pressure therapy in combination with a mechanical stabilizer because it would have provided a means for adjusting upper and lower teeth arches thereby increasing the opening of the user's breathing passageway to increase the effectiveness of treatments for breathing disorders such as OSA while remaining comfortable for the patient as taught by Thornton.

As to claim 5, Thornton teaches the positive airway therapy is CPAP (88).

As to claim 6, Pantino discloses in claim 7, that the device is used for the treatment of chronic fatigue, migraine headaches, tension headaches, muscle pain, muscle tenderness, heartburn which are symptoms of a known functional somatic syndromes.

As to claim 7, Pantino discloses upper (13) and lower (12) members of the airway stabilizer are of minimal thickness such that airflow and oral architecture are minimally impacted. Inherent in adjusting the airway stabilizer to fit a particular patient's mouth is making sure airflow is minimally impacted by monitoring for any airflow limitation including an inspiratory airflow limitation.

As to claim 11, Pantino as discussed above with respect to claim 1 also discloses the functional somatic syndrome of temporomandibular joint syndrome (col.5, lines 25-27 and col.8, line 50-51).

Claim 12 is substantially equivalent in scope to claim 1 and is obvious by Pantino in view of Thorton for the reasons set forth above with respect to claim 1.

Claim 15 is substantially equivalent in scope to claims 1 and 12 and is included in Pantino as modified by Thornton for the reasons set forth above with respect to claims 1 and 12.

As to claim 16, Thornton teaches the positive airway therapy is CPAP (88).

As to claim 17, Pantino discloses in claim 7, that the device is used for the treatment of chronic fatigue, migraine headaches, tension headaches, muscle pain, muscle tenderness, heartburn which are symptoms of a known functional somatic syndromes.

As to claim 18, Pantino discloses upper (13) and lower (12) members of the airway stabilizer are of minimal thickness such that airflow and oral architecture are minimally impacted. Inherent in adjusting the airway stabilizer to fit a particular patient's mouth is making

Art Unit: 3771

sure airflow is minimally impacted by monitoring for any airflow limitation including an inspiratory airflow limitation.

8. Claims 8, 9, 19, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pantino ('910) in view of Thornton ('048) as applied to claims 1, 5, 7, 11, 12, 15-18 above, and further in view of Kowallik et al.('766).

The difference between Pantino as modified by Thornton and claim 8 is the step of categorizing a patient who has an inspiratory airflow during sleep of approximately 51-100% of waking levels as an upper airway resistance syndrome patient.

Kowallik et al. (col.5, lines 12-20; col.6, lines 10-44 and col.8, lines 7-11) teach the step of categorizing a patient who has an inspiratory airflow during sleep of approximately fifty-one to one-hundred percent of waking levels as an upper airway resistance syndrome (UARS) patient for the purpose of detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA (col.3, lines 53-60).

It would have been obvious to further modify Pantino to include means for categorizing patients by type of respiratory disorder because it would have provided a means for detecting breathing patterns and to help a clinician differentiate between a patient with UARS and one suffering from OSA as taught by Kowallik et al..

As to claims 9, Kowallik et al. (col.5, lines 12-20 and col.6, lines 10-62) teach categorizing a patient who has an inspiratory airflow during sleep of approximately zero to fifty percent of waking levels as an obstructive sleep apnea/hypopnea (OSA/H) patient.

Art Unit: 3771

Claim 19 is substantially equivalent in scope to claim 8 and is included in Pantino as further modified by Kowallik et al. for the reasons set forth above with respect to claim 8.

As to claims 20, Kowallik et al. (col.5, lines 12-20 and col.6, lines 10-62) teach categorizing a patient who has an inspiratory airflow during sleep of approximately zero to fifty percent of waking levels as an obstructive sleep apnea/hypopnea (OSA/H) patient.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pantino ('910) in view of Thornton ('048) as applied to claims 1, 5, 7, 11, 12, 15-18 above, and further in view of Bennett ('686).

The difference between Pantino and claim 10 is observing alpha-delta sleep of such a patient to diagnose the functional somatic syndrome.

Bennett (col.1, lines 38-51) teaches observing alpha-delta sleep of such a patient to aid in diagnosing the functional somatic syndrome fibromyalgia.

It would have been obvious to modify Pantino to include monitoring patients for alpha-delta sleep to diagnose a functional somatic syndrome as taught by Bennett because it would have aided in the diagnosing more serious illnesses which may also exhibit sleep disorder symptoms as taught by Bennett.

Response to Arguments

10. Applicant's arguments filed 9/18/2006 have been fully considered but they are not persuasive.

Regarding the arguments directed towards 35 USC § 102(e) rejection on page 10, first full paragraph of the remarks, the Applicant has amended the claims to include the limitations of claims 4 and 15 into claims 1 and 12, respectively. Applicant has cancelled claim 4. However, Applicant has not cancelled claim 15. The scope of claim 15 remained unchanged. Therefore, the claims stand as rejected.

Regarding the arguments directed towards 35 USC § 103(a) rejection on page 11, first full paragraph of the remarks, the Applicant argues that because Pantino's mechanical oral appliance treats TMJ and bruxism with an oral appliance and it would not have obvious to have provided an airway stabilization technique to treat the functional somatic syndrome or symptoms of functional somatic syndrome. The Applicant further argues that Patino's mechanical oral appliance is not capable of positive airway pressure therapy.

Applicant agrees that Thorton discloses a CPAP device that treats conventional sleeping disorders like snoring and sleep apnea. Applicant argues that Thorton's device was not purposely built for treating functional somatic syndrome and symptoms. Therefore, it would not be expected that one skilled in the art would utilize Thorton's device to combat functional somatic syndrome and symptoms.

The Examiner believes Pantino's mechanical oral appliance is fully capable of stabilizing an airway. In column 5, lines 20 to 27, Pantino discloses the mechanical oral appliance reduces the possibility of the airway collapsing. Furthermore, Pantino disclose in column 5, lines 39-45, that his mechanical oral appliance considers CPAP devices for opening the oral airway in combination with his mechanical oral appliance. Pantino establishes that it well known in the art to use a mechanical oral appliance in combination with a CPAP device to prevent an airway from

Art Unit: 3771

collapse. This action prevents snoring, obstructive sleep apnea, and directly TMJ and bruxism (col. 5, ln. 46-47 and col. 5, ln. 25-27).

Thorton discloses an oral mechanical oral appliance in combination with a CPAP device provides an effective treatment for snoring, obstructive sleep apnea, and other breathing disorders. Thorton disclose in column 4, lines 44 to 58, device is capable of providing CPAP therapy for the purpose of opening the user's airway. Thorton establishes that it well known in the art to use CPAP devices with oral appliance to prevent a patient's airway from collapsing. Pantino's mechanical oral appliance provided with Thorton's CPAP device is capable of combating TMJ, bruxism (Pantino: col. 5, ln. 25-27), sleep disordered breathing, upper airway resistance syndrome, chronic fatigue syndrome, asthma, fibromyalgia, headache, heartburn (Pantino: claim 7), sleep apnea, snoring, and other breathing disorders (Thorton: col. 3, ln. 9-10), All of which are symptoms of or considered elements of functional somatic syndrome, per the Applicant disclose. Since the combined references show the same structure as claimed and there is no structure to prevent user from using the combined reference to perform the claimed method steps, the rejection for claims 8, 9, 15, 16, 19 and 20 stand has rejected.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 3771

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Brandt whose telephone number is 571-272-7199. The examiner can normally be reached on 8:30 AM to 4:30 PM; Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ACB



Adam Brandt

Examiner

Art Unit 3771


JUSTINE R. YUSUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

11/16/06